

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/473,789	06/07/95	CURTISS	R MEGAN-100-21

ELIE H. GENDLOFF  
HOWELL & HAERKAMP, L.C.  
7733 FORSYTH BLVD  
SUITE 1400  
ST. LOUIS MO 63105-1817

HM12/0927

EXAMINER

PORTNER, V

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

08/473,789

Applicant(s)

Curtiss

Examiner

Portner

Group Art Unit

1645



☒ Responsive to communication(s) filed on Dec 28, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-16, 20-32, 35-38, and 41-44 is/are pending in the application.

Of the above, claim(s) 5-7, 15, 21, 22, 25, 26, 36, and 38 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4, 8-14, 16, 20, 23, 24, 27-32, 35, 37, and 41-44 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

### **DETAILED ACTION**

Claim 45 has been canceled.

Claims 1-16,20-32, 35-44 are pending.

Claims 5-7,15,21-22,25-26, 36 and 38 stand withdrawn from consideration.

Claims 1-4,8-14, 16, 20, 23-24, 27-32, 37 and 41-44 are under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action

#### ***Rejections Maintained***

2. Claims 1-4,8-14,16,20,23-24, 27-32, 35, 37 and 41-44 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5,8,11,15-23,31,32,35,36,39-41,44-52 of U.S. Application Serial No.08/761,769 .

#### ***Rejections Withdrawn***

3. Claims 1-4, 8-14, 20,23,24, 27-29 and 37 rejected under 35 U.S.C. 102(e) as being anticipated by Molin et al (US Pat. 5,670,370), in light of Applicant's claim amendments.
4. Claims 1,4,10-12,20,27,41-44 rejected under 35 U.S.C. 102(b) as being anticipated by Curtiss, III, in light of Applicant's claim amendments.

Art Unit: 1645

5. Claims 1,4,10-12,20,27,41-44 rejected under 35 U.S.C. 102(b) as being anticipated by Curtiss, III, in light of Applicant's claim amendments.

**New Claim Limitations/New Grounds of Rejection**

6. Claims 1, 27 and 30 have been amended to recite the phrase "wild type gene of the microbial cell" and "wild type gene is inactivated in the cell".

***Claim Rejections - 35 U.S.C. § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-4,8-14, 16, 20, 23-24, 27-29, 30-32, 37 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claimed invention is directed to an isolated microbial cell that comprises a system that expresses an essential gene in a permissive environment, and a lethal gene in a non-permissive environment. The essential gene is any gene essential to viability and the lethal gene is any gene

Art Unit: 1645

that will cause microbial cell death. The essential gene has been defined to be a wild type gene of the microbial cell that is expressed in a permissive environment and the lethal gene is expressed in a non-permissive environment the microbial cell.

The claims require the expression of the essential gene, but the gene is inactivated. The number of wild type genes in the microbial cell has not been defined to be at least two copies of the wild type gene. The recitation of the phrase "wild type gene is inactivated in the cell" only finds antecedent basis in section (a) of the claim. If the essential gene is inactivated in the microbial cell, then how will it be expressed in a permissive environment? How the wild type gene is inactivated is broadly recited, and can be read to be a gene that is inactivated by any means, at any time. All living microbial cells express essential genes to maintain viability. Which of the essential wild type genes has been inactivated, but still allows the expression of other wild type genes is not distinctly claimed. Clarification, of the new claim limitations, is requested.

It was noted that Claims 27-29 recite the introduction of two genes into the microbial cell, but the antecedent basis problem still exists, such that the claim appears to be defining a method that introduces an essential gene and a lethal gene, but then the essential gene is inactivated. The gene can not be expressed and inactivated at the same time. Clarification of what has been inactivated could obviate this rejection.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

Art Unit: 1645

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-4,8-14, 16, 20, 23-24, 27-29, 30-32, 37 and 41-44 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is directed to a cell that expresses an essential gene that is a wild type gene and only expressed in a permissible environment, and contains a lethal gene that is expressed under conditions that are considered not to be permissible. The newly submitted claim limitation recites the wild type gene is inactivated.

All of the claims recite a dead cells that do not express the essential gene for viability. The microbial cell has been clarified to have an inactivated wild type gene by the Amendment submitted December 2000. With the essential gene is inactivated, the expression of the essential gene will not take place under any conditions, permissible or non-permissible. The functional limitations of section (a) have been contradicted through the recitation of "wherein the wild type gene is inactivated in the cell". The limited viability system must start with a viable cell. The cell would not be viable at all with an inactivated wild type gene.

The claimed invention is not enabled for a viability system when the essential gene for viability has been inactivated per Applicant's amendment newly submitted.

Art Unit: 1645

*Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

Art Unit: 1645

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp  
September 25, 2001

  
LYNETTE R. P. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600